K051739

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JUL 2 8 2005

500P 510k Submission

500P Transcranial and
Vascular Doppler
Multigon Industries, Inc.

SUMMARY

This summary of 510k safety and effectiveness information is being submitted in accordance with 21CFR part 807.92

1. Submitters name, address, phone number, contact person and preparation date:

Name: Multigon Industries, Inc.
1 Odell Plaza
Yonkers, N.Y. 10701
Phone: 914 376 5200 ext. 27
Fax: 914 376 6111
Email: wstern@multigon.com
Responsible person: William Stern

Official correspondent:
William Stern
Multigon Industries, Inc.
1 Odell Plaza
Yonkers, N.Y. 10701
Phone: 914 376 5200 ext. 27
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Email: wstern@multigon.com

Date of Preparation:
6/16/05

2. Proprietary Name:
Model 500P Pocket Transcranial and Vascular Doppler Spectrum Analyzer

Common /Usual Name:
Transcranial and Vascular Doppler
Diagnostic Ultrasound Transducer

Classification Name:
21 CFR892.1550 System, Imaging, Pulsed Doppler, Ultrasonic
21 CFR892.1570 Diagnostic Ultrasound Transducer

Classification Number:
90IYN
90ITX

3. Substantially Equivalent Devices

Multigon Industries, Inc. believes that the Model 500P Transcranial and Vascular Doppler Spectrum Analyzer and transducers is substantially equivalent to the following cleared devices:

Trade or Proprietary Name	Manufacturer	510(k) Number
Model 500V Transcranial and Vascular Doppler Analyzer	Multigon Industries.	K882755/A
Intra-View Transcranial Doppler	Rimed LTD	K974588
Explorer CVS Transcranial Doppler	Diagnostic Medical Sys.	K990517
Neurogard Transcranial Doppler	Medasonics,Inc.	K962796
Transpect Transcranial Doppler	Medasonics,Inc.	K872292
Model TC4040 Pioneer Transcranial Doppler	Eden EMS-Nicolet	K874684
Multidop Transcranial Doppler	DWL Electronische Sys	K930458

Comparison of Multigon Model 500P Transcranial and Vascular Doppler Spectrum Analyzer and Transducers with the predicate device Multigon Model 500V Transcranial and Vascular Doppler Spectrum Analyzer.

SPECIFICATION

	Model 500V	Model 500P
PROBES:	2 mHz PW 5 mHz CW	2 mHz PW 5 mHz CW 4 mHz CW 8 mHz CW

The 4 mHz CW probe and 8 mHz CW probe substantial equivalence to predicate devices is claimed by comparison to the Rimed Intraview TCD k974588 and to the DMS CVS System k990517.

500P 510k Submission		500P Transcranial and Vascular Doppler Multigon Industries, Inc.
DOPPLER TYPE	Bi- Directional	Bi- Directional
FREQUENCY RANGES	1,2,5,10,20,40 kHz	1,2,5,10,20 kHz
FREQUENCY OFFSET	0,20,40%	0,20,40,50 %
TIME AND FREQUENCY CALIPERS	YES	YES
STORAGE OF SPECTRAL DATA	104 seconds	2 hours
CALCULATIONS	Peak, Mean, Pulsatility Index Resistance Index, Systolic/Diastolic Ratio	Same Parameters
ANNOTATION	Date, Vessel I.D., Patient I.D. Patient Report	Same plus printed Report of waveforms

The printed report with the waveforms is substantially equivalent to that provided by the Explorer CVS device of Diagnostic Medical systems, cleared with k 990517. The printed report is also substantially equivalent to that provided on the Intraview TCD manufactured by Rimed LTD and cleared with k974588.

MONITORING MODE	NO	YES

For the Monitoring Mode for the 500P substantial equivalence is claimed by predicate devices as follows and previously cleared in the Pioneer model TC 4040 510k clearance k 874684 manufactured by Eden Medizinische Elektronik GmBH (EME) a subsidiary of Nicolet Biomedical, now called Viasys. Substantial Equivalence is also claimed by a predicate device manufactured by Rimed LTD, the model Intraview, 510k clearance k974588. The Monitoring Mode of the 500P is substantially equivalent in form and function to the above predicate devices.

	NO	YES
HITS (HIGH INTENSITY TRANSIENT SIGNALS EMBOLI DETECTION)		

The HITS (High Intensity Transient Signals) detection has been cleared in the Pioneer (TC4040) (510k number k874684) substantially equivalent predicate device manufactured by Eden Medizinische Elektronik GmbH, a subsidiary of Nicolet Biomedical, page 430 in their 510(k) submission described as follows: HITs indicator-EME assists in the indication and saving of High Intensity Transient signals (H.I.T.S.) by allowing physicians to customize the indication parameters to the study requirements and their personal preferences.

The HITS function is also present in a predicate Multi-Dop system (510k clearance k930458) Manufactured by DWL Electronische System GmbH and presented on page 477 of the original 510k submission.

The Multigon 500P HITS detection is substantially equivalent in form and function to the HITS detection in the two predicate devices above.

Conclusion: The Model 500P Transcranial and Vascular Doppler are substantially equivalent to the predicate devices described above in principles of operation, specifications, performance,safety and effectiveness.

4. DEVICE DESCRIPTION

The 500P device consists of a battery operated (also can be used with a medical grade AC adapter) Doppler and display unit with a choice of 2 mHz, 4 mHz, 5 mHz or 8 mHz transducers. The 2 mHz probe is a pulsed Doppler used for insonation of the adult intracranial arteries. The 4mHz , 5 mHz or 8 mHz CW probes are used for insonating the peripheral arteries. The Doppler and display unit contains a user interface, a display, system electronics, a memory storage card and a USB interface for an external computer.

All of the transducers are connected to the system using quick disconnect connectors.

The 500P Transcranial and Vascular Doppler provides the healthcare professional with information which can be used to determine the state of blood flow in the intracranial and extracranial vascular arteries.

5. PERFORMANCE STANDARDS

No performance standards have been established for the 500P Transcranial and Vascular Doppler under section 514 of the Federal Food and Drug Act. However the 500P Transcranial and Vascular Doppler has been designed to meet the following standards:

UL 2601-1 Safety Requirements for Medical Equipment
AIUM/NEMA UD 2 Standard for Real Time Dsplay of Thermal and Mechanical Output Indices on Diagnostic Ultrasound Equipment
AIUM/NEMA UD 3 Standard for Real Time Display of Thermal and Mechanical Output Indices on Diagnostic Ultrasound Equipment
IEC 1157 Declaration of Acoustic Power
IEC60601-1-2
IEC60601-2-37

6. INDICATIONS FOR USE

The 500P Transcranial and Vascular Doppler is to be used for the assessment of circulation in the adult cephalic, (intracranial and extracranial) and peripheral vascular vessels. It is to be used by trained medical personnel in hospitals, clinics, and physicians offices by prescriptions or doctors orders.

7. CONTRA-INDICATIONS

None known at this time.

8. COMPARISON TO PREDICATE DEVICES

The 500P Transcranial and Vascular Doppler has the same device characteristics as the approved predicate devices listed in item 3 above with the commonality of ultrasound transducers, principles of operation, and display of blood flow waveforms.

9. TEST DATA

The Model 500P Transcranial and Vascular Doppler has been subjected to extensive safety, performance testing, and validation before release. Final testing of the 500P included various performance tests designed to ensure that the device met all of its functional specifications. Safety tests have been performed to ensure the device complies with applicable industry and safety standards.

The Model 500P Transcranial and Vascular Doppler device labeling includes instructions for safe and effective use, warnings, cautions and guidance for use. It has therefore shown to be safe and effective.

10. LITERATURE REVIEW

A review of the literature pertaining to the safety of the 500P Transcranial and Vascular Doppler has been conducted and appropriate safeguards have been incorporated in the design of the 500P Transcranial and Vascular Doppler.

11. CONCLUSIONS

The conclusion drawn from these tests is that the 500P Transcranial and Vascular Doppler with transducers is substantially equivalent in safety and efficacy to the predicate devices listed in item 3 above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2005

Mr. William Stern
Official Correspondent
Multigon Industries, Inc.
One Odell Plaza
YONKERS NY 10701

Re: K051739
Trade Name: Model 500P Pocket Transcranial and Vascular Doppler Spectrum Analyzer
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN and ITX
Dated: June 24, 2005
Received: June 28, 2005

Dear Mr. Stern:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Model 500P Pocket Transcranial and Vascular Doppler Spectrum Analyzer, as described in your premarket notification:

Transducer Model Number

2 MHz Model 2MPB
4 MHz Model 4MPB
5 MHz Model 5MPB
8 MHz Model 8MPB

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known):

Device Name: Model 500P Pocket Transcranial and Vascular Doppler Spectrum Analyzer

Indications For Use: The 500P Transcranial and Vas~~cular~~ar Doppler is to be used for the assessment of circulation in the adult cephalic ,(intracranial and extracranial) and peripheral vascular vessels. It is to be used by trained medical personnel in hospitals, clinics and physicians offices by prescriptions or doctors orders. It is not to be used for Obstetrics.

Prescription Use __X__ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagwon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051739

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	~~Color~~ Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic				N						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: 2 MHz Transducer Model 2MPB for the Model 500P Transcranial and Vascular Doppler

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051739

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: 4 MHz Transducer Model 4MPB for the Model 500P Transcranial and Vascular Doppler

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051739

500P Transcranial and
Vascular Doppler
Multigon Industries, Inc.

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: 5 MHz Transducer Model 5MPB for the Model 500P Transcranial and Vascular Doppler

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

F-3

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051739

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: 8 MHz Transducer Model 8MPB for the Model 500P Transcranial and Vascular Doppler

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lagrow

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051739